U. S. FOOD AND DRUG ADMINISTRATION (FDA)

Department of Health and Human Services

[Docket No. 98P-0504]

Performance Standard for *Vibrio Vulnificus*

Executive Board members of the Association of Food and Drug Officials (AFDO) are pleased to submit our comments concerning the proposal to establish a "non-detectable" performance standard for *Vibrio Vulnificus* in raw molluscan shellfish.

As a professional organization which represents public health officials from all levels of government, industry, and academia, AFDO is very cognizant of the dangers associated with this marine bacterium and the risk created to the most vulnerable in our population.

AFDO views this matter in a similar fashion to other food products that are consumed raw or minimally processed and where new and emerging pathogens have created public health concerns. Certainly research and development of new safety controls are critical elements of an appropriate response to these incidents. As with all foods eaten raw, one has to be cognizant that there is always a safety risk, albeit a reduced risk when treatments which reduce organisms are used.

AFDO wishes to offer the following comments and concerns relative to the proposal:

1. While the AmeriPure Co. process is effective in reducing *Vibrio Vulnificus* to undetectable levels, is the same true for other pathogens of concern including other *Vibrios*, *Salmonella,* and *Norwalk* like viruses which have all been linked to illnesses from raw oyster consumption?

2. *Vibrio vulnificus* is a problem generally associated with higher water temperatures where higher levels of the organism exist. The organism has been isolated from both the Pacific and Atlantic Oceans, although the levels are much lower than those found in warmer Gulf of Mexico waters. It is not exactly clear how this effects pathogenicity, and it appears to us that more research is necessary in this area.

3. AFDO fully supports a performance standard that will achieve a "0" level of *Vibrio vulnificus* in molluscan shellfish. AFDO also supports a position that allows for the development of any technology that will achieve this goal. Had FDA mandated pasteurization for raw apple cider, it is unlikely other process controls would have been developed. We view this shellfish matter in a similar way.

AFDO believes the practical approach to this matter is not through regulation but through continued research, consumer education, and strict enforcement of harvesting, packing, and labeling requirements.

AFDO is encouraged by the data demonstrated with the AmeriPure Co. system, and we support its application as a matter of choice. Time should be permitted to allow for the development and testing of other means of achieving this performance standard so that small processors are not forced to close.

Submitted by: Joseph Corby, President
Association of Food and Drug Officials

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Association of Food and Drug Officials

THE NATIONAL UNIFORM FOOD LABELING ACT OF 1998

(Proposed)

Comments from the Association of Food and Drug Officials (AFDO)

The Executive Board of the Association of Food and Drug Officials is pleased to offer its comments on the proposed "National Uniform Food Labeling Act of 1998."

Section 2 - Labeling of Raw or Partially Cooked Foods

This proposal is for a consumer advisory related to foods which are raw, partially or lightly cooked. It is not comprehensive in the food items included. Other foods of animal origin which are not adequately cooked such as beef, lamb, pork, or poultry (particularly in the ground form) also carry a potential increased risk. The Food and Drug Administration's (FDA) Model Food Code addresses these additional foods of animal origin. Meat and poultry products should not be overlooked.

It may be a good idea to utilize already existing examples of language for the consumer advisory. It should not be necessary to duplicate the efforts of FDA, the Conference for Food Protection (CFP), and industry which has already put a concerted effort into obtaining focus group input on the issue of consumer advisory language.

It would be of interest to learn whether the FDA/CFP focus groups considered the use of a universal hazard symbol in conjunction with the warning statement and whether it had the appropriate intended impact. We have questions about its use for this purpose.

Section 3 - Labeling of Frozen Fish and Shellfish

A number of states do require a "Frozen and Thawed" labeling statement on retail packaged fish and shellfish when appropriate. Extension of this requirement to meat and poultry, in our view, would be very acceptable to consumers. It would, however, require a clear definition and understanding of what the term "frozen" means.

Florida requires any food previously frozen and then thawed to have consumer information by placard or label indicating that the product was previously frozen. There are many entree items that are displayed refrigerated that are previously frozen. These items are not limited to seafood.

Section 4 - Statement of Origin

Normally, country-of-origin requirements are the jurisdiction of the Federal Trade Commission/ U.S. Customs Service and not FDA. Effective enforcement down to the retail level would require multi-agency cooperation. With international trade implications, requirements for statement of origin labeling cannot be handled as simply as it is proposed here.

If the underlying reason for this requirement is consumer perception and choice related to safety, we should really place our number one emphasis on programs and enforcement resources that will help ensure these products are safe in the first place - no matter what their origin.

As the proposal is written, domestic produce as well as imported produce would need to be labeled with the country-of-origin. U.S. retailers (and consumers) may not see the particular need for labeling domestic produce with "Product of USA," as this may be considered the default. While some would agree with the proposal as a means of providing choice for the consumer, it is likely that a majority of retailers would say it is impractical and a tremendous burden.

Florida enforces country of origin labeling requirements with respect to raw fruits and vegetables with little reported problems. This state would be a good source of information on this issue.

Section 5 - Freshness Date

This issue really appears to be a big black hole. "Freshness date" is not likely the appropriate term. According to FDA, the term "fresh" suggests or implies that the food in unprocessed, in the raw state, and has not been frozen or subjected to any thermal processing or any other form of preservation (with few exceptions). *See 21 CFR 101.95.* The proposal appears to be in conflict with FDA's application of the word "fresh" and includes foods which may be outside FDA's definition.

The proposal appears to require date labeling for *all* food products. Companies may be tempted to put an arbitrary date on an item, perhaps several months or years out, to simply satisfy the regulatory requirement for date labeling. They may choose not to, or be unable to, put a concerted effort into the determination of a truly appropriate and scientifically meaningful date related to diminution of quality, nutrient availability, etc. Variations in processing, handling, and storage may dictate a widely differing range of appropriate "freshness" dates for a multitude of products. Meaningful enforcement by regulatory officials of the choice of dates would be difficult. Enforcement action against violations of these date labeling rules may be difficult to hold up in court.

On the other hand, there are some instances where dating for safety purposes is backed by sufficient scientific evidence and can be appropriately applied, e.g., sell-by-dates for smoked fish. Regulatory agencies can provide specific parameters for this type of dating requirement.

Section 6 - Food Labeled as Natural

"Natural" has only been defined by the Federal Trade Commission, and FDA has never formally adopted it. Instead, FDA has policy guidance for use of the term. FDA also allows use of the term "natural" in the labeling of processed foods in addition to minimally processed foods. Some manufacturers of processed food products make statements such as "all natural ingredients." FDA's current policy appears to allow this, while the proposal appears to ban this usage. Overall, It would be beneficial for FDA to codify their policy to help remove "the gray area" and make it more enforceable.

Salsa is an example of a product which may undergo acidification or thermal processes in order to make it a safe product. The proposal appears to ban use of the term "natural" for products like this, which are otherwise minimally processed. In our opinion, the proposal appears too restrictive.

To the best of our knowledge, FDA has never actively defined "natural color." Instead, FDA has consistently indicated that color added to a product where that color is not already a component of that product is an "artificial color." Many cheese manufacturers have a desire to list annatto coloring as a "natural color" due to its vegetative origin. However, FDA objects to this terminology and views annatto as an "artificial color" since it is not a naturally occurring constituent in the food. Theoretically, the term "natural color" could be used, for example, if grape skin extracts are used to intensify the color of grape juice or some similar application. Public perception is that "natural" simply means "not synthetic."

Section 7 - Labeling of Kosher and Kosher-Style Foods

Perhaps the law should specify that a food can only be labeled kosher when it is approved by a certifying agency in accordance with Orthodox Jewish religious standards and the label identifies the certifying agency. it also appears that currently existing certifying agencies have some differences of opinion about what is and is not acceptable to be deemed "kosher."

The terms "kosher-style" or "kosher-type" are used to indicate that the food being served or sold is not kosher for any of a variety of reasons. We have received no complaints about the use of this terminology and believe that people affiliated with the Orthodox Jewish religion understand what these terms mean.

Section 8 - Unit Pricing

Idealistically, unit pricing seems like a good idea. However, unit pricing for all foods appears to be impractical and especially burdensome to retailers. It may be disproportionately expensive for small businesses. Unit pricing also does not seem practical for ready-to-eat meals or vending machine foods. If all food products were involved in this requirement, enforcement at the retail level would require substantial regulatory resources.

The proposal as written is also anti-metric. The choice of units for comparison is severely limited - pounds, pints or quarts, and one hundred-count. We do not compare the price of two-liter bottles of soda on the basis of pints or quarts.

Section 9 - Grades and Standards for Farm Products

The scope of "farm products" needs to be defined. It could include a wide variety of products such as fruits and vegetables, eggs, honey, and maple syrup to name a few. It is not clear how the decision will be made and by whom if grading is "customary" in the industry. The federal government or some state governments may currently have grading regulations for certain products, while others may not. Perhaps there is only regional interest in the grade of certain products.

It is also not clear whether the intention of the proposal is to provide grade labeling for consumers. Potatoes and some other vegetables are labeled with a grade at retail, many are not. For other commodities, such as cheese, grade standards may be more of a wholesale buyer issue rather than a consumer issue. In either case, commodity quality grades are normally the purview of USDA, not FDA.

Effective enforcement down to the retail level would require multi-agency cooperation. Additional resources for enforcement and education of both industry and consumers would be critical to its success. A requirement for grade labeling without enforcement has no credibility.

Section 10 - Regulations

The proposal calls for the type size of all of the newly required label statements to be no smaller than the net quantity declaration, and in many cases larger! We question the wisdom of requiring these statements to be larger than the majority of other currently required label statements. Ingredient statements only need to be 1/16" high, or in some cases 1/32" high.

Already, packagers *frequently* complain to regulatory officials that they do not have room for all of the government-required label statements on their packages. By mandating that these statements be placed on the principal display panel or the information panel (and in such a large type size), it may be necessary to bump other required information like the "nutrition facts" to other panels. Packagers claiming lack of label space may loudly complain and may insist on using the linear format for the "nutrition facts," which is far less desirable in terms of consumer readability. Compliance with NLEA requirements just a few years ago forced many packagers to use second or additional labels on their packages. Compliance with this proposal will likely increase costs for additional labels.

AFDO's comments on the proposed bill should not be construed as an endorsement. In fact, commenters did not demonstrate uniform support for the proposal. For instance, one commenter suggested that another section be included which would require specific refrigeration labeling requirements already endorsed by AFDO. Another commenter believes that combining labeling requirements that combine issues pertaining to quality, religion, economics, and food safety is inappropriate.

The proposal appears to be quite labor intensive and will require additional money and personnel from both industry and government enforcement perspective. Industry will not likely bear the entire cost, but will pass it along in the form of increased prices to consumers. It would also appear that a major portion of the enforcement of these requirements will be at the retail/restaurant level where FDA rarely inspects. Care should be taken to avoid unfunded mandates for states to enforce. Both the capacity and priority for government to enforce these new requirements needs to be taken into account.

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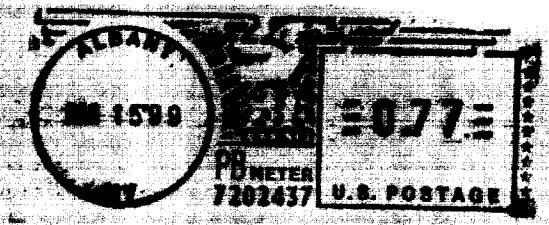

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